



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2023-0225; FRL-10919-02-OCSP]

### O-Benzyl-P-Chlorophenol (OBPCP); Exemption from the Requirement of a Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes exemptions from the requirement of a tolerance for residues of ortho-benzyl-para-chlorophenol, potassium 2-benzyl-4-chlorophenate, and sodium 2-benzyl-4-chlorophenate on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. These tolerance exemptions are established on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA), in order to implement the tolerance actions EPA identified during its review of these chemicals as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2023-0225, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Anita Pease, Antimicrobials Division (7510M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-0736; email address: [ADFRNotices@epa.gov](mailto:ADFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are a pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2023-0255 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk in the Office of the Administrative Law Judges on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Notwithstanding the procedural requirements of 40 CFR 178.25(b), the Office of the Administrative Law Judges has issued an order urging parties to file and serve documents with the Tribunal by electronic means only. *See Revised Order Urging Electronic Filing and Service* (dated June 22, 2023), <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2023-0225, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Background**

### *A. Proposed Rule*

In the **Federal Register** of May 5, 2023 (88 FR 29010) (FRL-10919-01-OCSPP), EPA proposed to establish exemptions from the requirement of a tolerance for residues of the antimicrobial pesticides ortho-benzyl-para-chlorophenol, potassium 2-benzyl-4-chlorophenate, and sodium 2-benzyl-4-chlorophenate in food resulting from application to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. The Agency had identified the need for the exemptions as part of the registration review process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(g), and published a proposed rulemaking under its authority to initiate tolerance rulemakings under the FFDCA section 408(e), 21 U.S.C. 346a(e). That proposal noted that the new exemptions would supersede the current exemption for ortho-benzyl-para-chlorophenol under 40 CFR 180.940(c) (listed as phenol, 4-chloro-2-(phenylmethyl)-, an alternative name for ortho-benzyl-para-chlorophenol), which would be removed from the regulations as unnecessary and redundant.

As noted in the proposal, the O-Benzyl-p-Chlorophenol (OBPCP) Interim Registration Review Decision (OBPCP ID) identified the need for these exemptions based on existing registered pesticide uses, and the underlying risk assessment concluded that there were no risks of concern associated with these uses. Consequently, EPA concluded that the exemptions from the requirement of a tolerance for residues of ortho-benzyl-para-chlorophenol, sodium 2-benzyl-4-chlorophenate, and potassium 2-benzyl-4-chlorophenate, when used in antimicrobial formulations applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils when used at concentrations not to exceed 2,080 ppm in end-use formulations, would be safe. Electronic copies of the OBPCP ID and other documents are available in EPA docket number EPA-HQ-OPP-2011-0423, which can be found at <https://www.regulations.gov>.

*B. What is the Agency's authority for taking this action?*

Under section 408(e) of the FFDCA, EPA can establish an exemption from the requirement of a tolerance for residues of a pesticide chemical after publishing a proposed rule and providing 60-day period for public comment. 21 U.S.C. 346a(e). EPA published the proposed rule on May 5, 2023, and provided 60 days for public comment (until July 5, 2023).

### **III. Final Rule**

#### *A. Comments*

No substantive comments were submitted in response to the proposed rule.

#### *B. Determination of Safety*

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue ....”

As noted in the proposed rule, EPA reviewed the available scientific data and other relevant information as part of registration review and in support of this action. Based on that review, EPA’s proposed rule concluded that the exemptions would be safe.

Since no comments were filed, EPA’s assessment of the potential for risks from exposure to these pesticide chemicals and conclusions about the safety of these exemptions remains

unchanged. Therefore, based on the lack of any aggregate risks of concern, EPA concludes that these exemptions from the requirement of a tolerance for residues of ortho-benzyl-para-chlorophenol, sodium 2-benzyl-4-chlorophenate, and potassium 2-benzyl-4-chlorophenate, including the limitation for the end-use formulation concentration of each of these pesticides to not exceed 2,080 ppm, are safe, i.e., there is a reasonable certainty that no harm will result from aggregate exposures to ortho-benzyl-para-chlorophenol, sodium 2-benzyl-4-chlorophenate, or potassium 2-benzyl-4-chlorophenate, when used in accordance with the terms of the respective exemptions. In addition, EPA has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residues, in accordance with FFDCA section 408(b)(2)(C).

#### **IV. Conclusion**

Therefore, exemptions from the requirement of a tolerance are established for residues of ortho-benzyl-para-chlorophenol, potassium 2-benzyl-4-chlorophenate, and sodium 2-benzyl-4-chlorophenate, when used on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils, with a limitation in concentration of 2,080 ppm in end-use formulations. In addition, EPA is removing the existing exemption in 40 CFR 180.940(c) for residues of phenol, 4-chloro-2-(phenylmethyl)-, as it is unnecessary and redundant upon the establishment of these new exemptions.

#### **V. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders#influence>.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review*

This action is exempt from review by the Office of Management and Budget (OMB) under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011) because it establishes tolerance exemptions under FFDCA section 408.

*B. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

*C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule has no net burden on small entities subject to the rule. As discussed in the proposed rule, this takes into account the EPA analysis for the establishment and modification of tolerances. Furthermore, the Agency did not receive any comments on these conclusions as presented in the proposed rule.

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

*E. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132, August 10, 1999 (64 FR 43255). It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175, November 9, 2000 (65 FR 67249), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potential effective and reasonably feasible alternatives. This action is also not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (*See Unit V.A.*) and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA's *Policy on Children's Health* applies to this action.

This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . .” (FFDCA 408(b)(2)(C)). Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific and other data and other relevant information in support of these final tolerance actions. The Agency's consideration is documented in the pesticide specific registration review decision documents. See the discussion in Unit III. and access the chemical specific registration review documents in each chemical docket at <https://www.regulations.gov>.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer Advancement Act (NTTAA)*



This action does not involve technical standards under NTTAA section 12(d), 15 U.S.C. 272.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations. As discussed in more detail in the pesticide specific risk assessments conducted as part of the registration review for the pesticides identified in Unit II., EPA has considered the safety risks for the pesticides subject to this rulemaking and in the context of the tolerance actions set out in this rulemaking. EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. Furthermore, EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 25, 2024.

**Anita Pease,**

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Amend § 180.940 by:

a. Adding in alphabetical order the entries “Ortho-benzyl-para-chlorophenol”, “Potassium 2-benzyl-4-chlorophenate”, and “Sodium 2-benzyl-4-chlorophenate” to table 1 to paragraph (a).

b. Removing the entry “Phenol, 4-chloro-2-(phenylmethyl)-” from the table in paragraph (c).

The additions read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \*

(a) \* \* \*

Table 1 to Paragraph (a)

Pesticide Chemical	CAS Reg. No.	Limits
* * *	* * *	* * *
Ortho-benzyl-para-chlorophenol	120-32-1	When ready for use, the end-use concentration is not to exceed 2080 ppm
* * *	* * *	* * *
Potassium 2-benzyl-4-chlorophenate	35471-49-9	When ready for use, the end-use concentration is not to exceed 2080 ppm
* * *	* * *	* * *
Sodium 2-benzyl-4-chlorophenate	3184-65-4	When ready for use, the end-use concentration is not to exceed 2080 ppm
* * *	* * *	* * *

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